REMARKS

Reconsideration of claims 11-17 and 20-25, and new claims 26 - 53 is respectfully requested. Claims 11-13, 16, and 20-21 are amended. The ranges recited in new claims 26 and 27 are supported in-part by the amount of polyol plasticizer recited in Example 27 (compositions B, C and D). Applicants respectfully request that the rejection under 35 USC 112, second paragraph be withdrawn as the language at issue has been deleted from the claims.

The rejection of claims 11-17 and 20-25 under 35 USC 102(e) as anticipated by, or obvious, over Peltonen et al. (US 6,780,903) or Haasmaa et al. (US 6,656,984) is respectfully traversed with respect to the amended claims.

The Office Action asserts that Peltonen describes the use of stearic acid and cites to col. 5, lines 3-14. The Office Action also cites to the "many Examples", and the constituents recited at column 5, lines 38-43, "to be within the limits claimed except the stearic acid component." Pages 4-5. "As such, the instant claims are deemed to be at least obvious, if not anticipated, by the teaching of the [Peltonen] patent." Page 5. Applicants respectfully disagree with this conclusion for the reasons stated below. Because the disclosure of Peltonen and Haasmaa are near identical, Applicants apply the same arguments to both references, and cite to Peltonen.

Applicants submit that Peltonen or Haasmaa do not anticipate because as the Office Action recognizes there is no stated limits to the amount of stearic acid present, and more importantly, there is no teaching in Peltonen to even use stearic acid or its salt in the disclosed polymer compositions. The only reference to the term "C_{12-22} fatty acid or salt" (claims 12, 20 and 23) in Peltonen is the disclosure regarding the making of the starch ester. Peltonen, col. 4, lines 24-46. As described "[i]t has proved advantageous to use a starched-based component derived from an ester formed by starch and one or several aliphatic C_{2-24} carboxyl acids." "The carboxylic acid component may, however, even be derived from a saturated or an unsaturated native fatty acid. Examples of these include . . . stearic acid". Id. The disclosure goes on to describe how one can prepare a modified starch with fatty acid esters. Because there is no teaching in Peltonen that a "C_{12-22} fatty acid or salt" is a stand alone ingredient of the disclosed compositions, the rejection under § 102(e) is improper.

The same arguments can be made against the rejection under § 103(a) because there is no suggestion in Peltonen or Haasmaa to use stearic acid or its salt as in the disclosed compositions other than in the preparation of a starch ester. Again, the fatty acid is not a recited or suggested component of the disclosed polymer compositions.

The Office Action further asserts that "this component [fatty acid] is recited [in Peltonen] for the same purpose as described in the application." Id. Applicants submit that there is no support for this conclusion. The compositional limit of the fatty acid or stearic acid is not disclosed because stearic acid or its salt is not used as one of the ingredients in the polymer compositions described in Peltonen/Haasmaa, and therefore, stearic acid is not used for the same purpose. Rather, the fatty acids are used to prepare the starch ester. Accordingly, Applicants respectfully request that the rejection of claims 11-17 and 20-25 under §§ 102(e), 103(a) over Peltonen or Haasmaa be withdrawn.

The rejection of claims 11-17 and 20-25 under 35 USC 103(a) as obvious over Silbiger (US 6,284,838) in view of Buehler et al. (US 5,316,578) and Frische et al. (US 5,374,304) is respectfully traversed with respect to the amended claims.

Silbiger describes a biodegradable composition that is prepared by heating a lignin material with a protein. The focus in Silbiger is the interaction that occurs between the lignin material and the protein. Col. 1, line 65 to Col. 5, line 67. "It is to be assumed that the lignin and the protein associate or bind together so that after heating a lignin/protein reaction product is formed." Col. 2, lines 35-37. "In order to produce the composition of the present invention it is convenient to mix the . . . lignin containing material with the protein . . . and subsequently adding the additives. Col. 2, line 65 to col. 3, line 1. Silbiger also discusses the weight ratios of lignin material to protein. Col. 3, lines 18-23.

Silbiger also describes that a portion of the lignin/protein reaction product can be replaced by starch. Col. 8, line 28-62. Silbiger provides a long list of different starches that can be used in the compositions. This list includes starches derived from vegetables such as potato, corn rice. Potato and corn are listed as preferred starches. The starch can also be a modified starch, e.g., a starch ester. "In replacing the lignin partially by starch, the ratio of lignin to starch is preferably 10:1 to 1:10, . . . preferably 5:1 to 1:1." Col. 8., lines 24-27.

The polymer compositions described in Silbiger can also contain one or more additives. The provided list of additives includes polyvinyl alcohols and fillers such as cellulose fibers, starch esters or wood powder. The amount of filler present in the composition can be as much as 50 wt%, but preferably 5-15wt%. Col. 6., lines 1-36. The composition can also include plasticizers. Col. 6, lines 53-63.

In summary, Silbiger broadly describes a vast number of different biodegradable compositions given the very large compositional ranges in which each recited component can be present in the compositions. These compositions can be summarized as follows if divided into two major components: (i) the lignin/protein/starch component; and (ii) the other additive component.

The lignin/protein/component is said to be present in at least 20 wt%, preferably at least 80 wt% of the total composition. Moreover, a portion of the lignin material can be replaced by a modified starch. The amount of lignin material that can be replaced is from a weight ratio of lignin:starch of 10:1 to 1:10, preferably 5:1 to 1:1. Given the broad ranges for component (i), this alone can provide a number of different compositions in the thousands. For instance, do the compositions contain 80% or 20% component (i), and of this, does component (i) contain a lignin:starch ratio of 10:1 or 1:10. No one really knows how much of what is actually in component (i) because of the enormous compositional ranges disclosed for each type of compound in component (i). We are not finished, however, because we still have component (ii) to deal with.

Like component (i), component (ii) can be present from 0.2 to 80 wt%, preferably 5 to 40 wt% of the total composition. One type of compound in component (ii) is a polyvinyl alcohol (PVA). How much PVA is actually in the disclosed compositions? Silbiger says that the PVA will account for 5-40 wt%, preferably from 10 to 25 wt%. Component (ii) can also include a polyol plasticizer. The compositional range of the plasticizer is from 0.5 to 40 wt% preferably from 1.0 to 10 wt% of the total composition.

Applicants submit that such a broad disclosure fails to describe any particular biodegradable composition that would be recognized by one of ordinary still in the art. *In re*

Jones, 958 F.2d 347, 350 (Fed.Cir. 1992). Perhaps, one of ordinary skill can get a better picture from the Examples provided in Silbiger, which we summarize in Table 1 below.

Table 1

Ex.	Parts of Ingredients	Ex.	Parts of Ingredients (wt%)
1	5 protein	4	50 product of Ex. 1, 2 or 3
	35 water		12.5 PVA
	60 lignin		5 glycerin
	5 glycerin		
2	18 protein	5	100 product of Ex. 1, 2 or 3 (23.5)
	200 water		205 poly-2-caprolactone (48.2)
	42 lignin		50 PVA (11.8)
	8 glycerin		50 ethylene-vinylalcohol copolymer (11.8)
	80 sawdust		15 polyethylene glycol (3.5)
			5 sodium stearate (1.2%)
3	18 protein		
	300 water		
	40 lignin		
	8 glycerin		
	60 saw dust		

First, none of the provided Examples contain any form of a modified starch. Again, consistent with the specification as a whole, the disclosed Example compositions focus on lignin/protein/other additive(s). Moreover, the polymer composition of Example 5 contains nearly 50 wt% of a thermoplastic, biodegradable polyimide (polyester), and is nothing at all like Applicants' claimed compositions. Second, the total amount of polyvinyl alcohol polymer is about 23.5 wt% (PVA and ethylene-vinylalcohol copolymer), which is more than twice the amount than the claimed compositions. Applicants submit that the stated Examples would not lead or motivate one of ordinary skill to the claimed compositions.

In making a *prima facie* case of obviousness, the examiner "must consider the entirety of the disclosure made by the references, and avoid combining them indiscriminately." *In re Ehrreich,* 590 F.2d 902, 909 (CCPA 1979). The examiner's reliance on Buehler and Frische do not overcome the many deficiencies in the teachings or suggestions of the Silbiger disclosure. The Office Action appears to hand select the claimed ingredients from several references all of which are related to the making of biocompatible polymers without any motivation or suggestion in the references to make that combination. Moreover, there is no suggestion in the cited art that the proposed combination of disclosed polymer compositions would likely provide a reasonable expectation of a successful biodegradable polymer composition. Without more the proposed combination of references under section 103(a) is improper.

The Federal Circuit has repeatedly emphasized that a patent claiming a combination of old elements is subject to the same patentability analysis as any other patent. According to the Federal Circuit, "[t]here is no basis in the law ... for treating combination inventions any different than other inventions." *Brentingson Fishing Equipment Co. v. Shimano American Corp.*, 8 U.S.P.Q. 2d 1669, 1672 (Fed.Cir. 1988) ("The focus under section 103 is not whether each element in a claimed invention is old and unpatentable, but whether 'there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination'.").

Thus, the Federal Circuit has repeatedly struck down PTO and Board decisions rejecting claims under section 103 where there is no suggestion or motivation in the prior art to combine the teachings of the two or more cited references. This is especially true in the context of combination inventions. In such cases, the court often finds that the PTO and Board improperly asserted a *prima facie* case of obviousness based on the teachings of the Applicant's own disclosure. *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998). According to the *Rouffet* Court:

> As this court has stated, 'virtually all inventions are combinations of old elements.' *** Most, if not all, inventions are combinations and mostly of old elements. Therefore an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed

> invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be 'an illogical and inappropriate process by which to determine patentability'. (citations omitted)
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> To *prevent the use of hindsight* based on the invention to defeat patentability of the invention, this court requires the examiner to show *a motivation to combine* the references that create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, ... *with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.* (emphasis added).

Id. Thus, one skilled in the art must be motivated by some teaching in the references to make the specific combination claimed.

As stated in *Rouffett*, the law "requires the examiner to show a motivation to combine the references" in the absence of any knowledge of the claimed invention. The references must suggest to a person of ordinary skill to select the elements (and their respective amounts) from the cited art in the manner claimed. The present rejection of the claims under section 103(a) fails this very important test.

With respect to Buehler, the Office Action recognizes that the "reference fails to show the inclusion of a PVA consitiuent". Silbiger discloses 5-40% by weight, preferably 10-25% by weight, and Example 5 discloses nearly 25% by weight of PVA. No doubt, the presence of PVA-like polymer is a necessary component in the Silbiger compositions so why would one of ordinary skill in the art be motivated to combine the teachings of Buehler with Silbiger. Applicants submit there is no such motivation, and therefore, the Office Action fails to present a *prima facie* case of obviousness. Also, Buehler describes adding the metal stearate as an emulsifier with a urea or urea derivative. One of ordinary skill in the art would then question if one would actually need the emulsifier (stearic acid) in the absence of the urea compounds.

At best, Frisch might suggest to one of ordinary skill that one should try and substitute some of the lignin material in Silbiger with the special amylose materials because there is a suggestion in Silbiger to substitute some of the lignin with a starch material. However, even if one were to make this substitution that alone is insufficient to reject the claims under section 103(a) as there is no reasonable expectation that such a combination would lead to a successful

polymer composition. In addition, there is no teaching in either Silbiger or Frisch to make a biocompatible polymer composition with the selected amounts of low polymer (e.g., PVA) low plasticizer and a set amount of a "C_{12-22} fatty acid or salt". Accordingly, Applicants respectfully request that the rejection under § 103(a) be withdrawn.

The examiner is reminded that the claims are limited to a biodegradable polymer consisting essentially of the recited constituents present in their respective claimed range. Also, "claims should not be considered in the abstract, particularly when the invention is the result of a selection or screening process." *In re Tomlinson*, 363 F.2d 928, 931 (CCPA 1966).

Although Applicants submit that a proper prima facie case of obviousness has not been presented in the Office Action, Applicants discuss the experimental data provided in the application in support of the patentability of the presently pending claims. In particular, Applicants focus on compositions 15-26 (Page 8) as well as compositions A to E (Example 27) and the properties of those compositions under both high and low relative humidity, Table 6 and Table 7.

Examples 15-22 demonstrate the significant affect stearic acid has on the observed quality of polymer sheet. As observed in Example 15 (not claimed) the absence of stearic acid provides a "rough surface". The stearic acid concentration was then varied from 0.4 wt% to 5 wt%. It is noted that only Examples 16, 17 and 18 encompass the pending claims, with the following stearic acid concentrations; 0.4 wt%, 0.8 wt% and 1.2 wt%, respectively. For these Example compositions a "nice" formed sheet is observed. However as one exceeds 1.5 wt% stearic acid, the quality of sheet begins to decrease in relation to the amount of stearic acid present above 1.5 wt% as is apparent with Example Compositions 19-22. The other components in Examples 16-18 include a modified amylose 36%, a natural wheat starch 36%, polyvinyl alcohol 8%, glycerol (polyol plasticizer) 10%, and water 10 %.

Similar results were observed with Examples 23-26 in which the stearic acid was kept constant at about 1.0 wt%, the polyvinyl alcohol at about 8 wt% and portions of the glycerol was replaced with water (certainly a less costly component). What one observes is that the modulus and yield strength of the polymer sheet increases at high and low relative humidity conditions as

the amount of water increases. Also, the substitution of plasticizer for water has little effect on elongation at 15% relative humidity.

Applicants submit that there is no teaching in the cited art that one can actually directly substitute water for a known polyol plasticizer at such low levels of polyvinyl alcohol and still obtain a functional biodegradable polymer.

The claims are further supported by the 1.132 Declaration of Gregor Bruce Yeo Christie filed in parent application 09/857,611, portions of which are provided below.

> 8. This formulation was developed from extensive research to find an optimum mix that gave satisfactory properties and processability at a cost that was comparable to that of currently used polymers. The fast biodegradability of the blends is dependent on both the starch and the other polymer component being water soluble. The major reduction in cost was achieved by reducing the amount of polymer in component b). Cost is also reduced by reducing the amount of non water plasticizer to below 10%.
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> 9. This formulation allows the extrusion processing to operate without caking of the extruder and without the need to vent the die. The polymers are blended for processing to form a melt at relative low temperatures of 130°C to 160°C. The die temperatures for the process can be maintained within the range of 85°C to 105°C which is much lower than was possible with prior art formulations. Operating at lower die temperatures reduces the need for venting and improves the performance characteristics of the polymer blend. These processing characteristics are derived from the combination of modified starch, natural starch and lower proportions of the water soluble non starch polymer as well as the inclusion of water as the essential plasticizer and a polyol as an optional additional plasticizer.

Applicants submit that there is no teaching in the cited art that one can actually make a commercially successful polymer product with such low levels of polyvinyl alcohol and plasticizer. Applicants also submit that the claimed combination of each component in the polymer composition and present in the claimed amounts is not taught or suggested in the cited references. One of ordinary skilled in the art would not be motivated to combine the teachings of each reference as proposed in the Office Action. Nor would one of ordinary skill in the art have any reasonable expectation of success that the claimed compositions would provide a successful polymer product.

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In view of the above Amendment, applicant believes the pending application is in condition for allowance.

Please charge our Deposit Account No. 22-0185, under Order No. 21854-00019-US1 from which the undersigned is authorized to draw for all fees associated with this Amendment.

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Respectfully submitted,

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